**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,<br><br>*Plaintiffs,*<br>v.<br><br>JOHNSON & JOHNSON, INC. and CORDIS CORPORATION,<br><br>*Defendants.* | **REDACTED – PUBLIC VERSION**<br><br>C.A. No. 07-333-SLR<br>C.A. No. 07-348-SLR<br>C.A. No. 07-409-SLR |
| BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,<br><br>*Plaintiffs,*<br>v.<br><br>JOHNSON & JOHNSON, INC., CORDIS CORPORATION, and WYETH,<br><br>*Defendants.* | C.A. No. 07-765-SLR |

**BSC'S ANSWERING BRIEF IN OPPOSITION TO JOHNSON & JOHNSON, INC. AND CORDIS CORPORATION'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT OF CLAIM 9 OF THE '3286 PATENT**

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### CASES

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively, "BSC") respectfully submit this brief in opposition to the motion of Defendants Johnson & Johnson, Inc. and Cordis Corporation (collectively, "Cordis") for partial summary judgment of infringement of claim 9 of U.S. Patent No. 7,233,286 ("the '3286 patent").

## I. INTRODUCTION

Although Cordis has asserted 33 claims of the '3286 patent (and no fewer than 55 claims in total), it has moved for summary judgment only as to claim 9 of the '3286 patent (which depends from claim 1). It is no mystery why Cordis chose to focus on this claim; Claim 9 is among the broadest in a set of overly broad claims – claims so general that their language, if interpreted as Cordis urges, would clearly encompass the prior art. Indeed, some of the claim language – *e.g.*, "macrocylic lactone analog" – is so unrestrictive that it potentially embraces many thousands of chemical compounds.[1]

Claim 9 should not be read as broadly as Cordis urges. The '3286 patent envisions a polymer/drug coating applied directly to the stent. In the case of PROMUS, a drug-free homopolymer primer layer coats the stent. Then, a copolymer blended with everolimus is applied over that primer layer. To read claim 9 on the PROMUS stent, Cordis must either disregard the separate primer layer or elide it with the layer containing the copolymer and drug

[1] As discussed in Plaintiffs' Opening Brief in Support of Their Motion for Summary Judgment of Invalidity of U.S. Patent Nos. 7,217,286, 7,223,286, 7,229,473, and 7,300,662 under 35 U.S.C. § 112 (D.I. 259 in C.A. 07-765-SLR), the asserted patents (including the '3286 patent) fail to offer any insight into how one of ordinary skill in the art at the time of the invention would isolate a "macrocyclic lactone analog" (or, in the case of the '662 patent, a "macrocyclic triene analog") with the therapeutic properties required in the claims. (*See id.* at 13-18.) The asserted patents also fail to provide any guidance as to how one would distinguish a structural analog of rapamycin that falls within the claims from one that does not. (*See id.* at 29-32.) An examination of the patents' specification shows that the inventors themselves were not in possession of an invention employing an "analog" of rapamycin, and the inventors' sworn testimony confirms this point. (*See id.* at 19-21.) For these reasons, the asserted claims are indefinite because they are (1) not enabled, (2) inadequately supported by the patents' written description and (3) indeterminate.

mixture over it. In so doing, Cordis runs afoul of established principles of claim construction as well as clear statements in the '3286 patent itself. Similarly, Cordis's position in its motion depends on its incorrect interpretation of "a biocompatible polymer/drug mixture" – an interpretation that contradicts the express definition set forth in the '3286 patent. When claim 9 is properly construed, it is clear that the PROMUS stent does not infringe.

## II. NATURE AND STAGE OF THE PROCEEDING

BSC seeks a declaration that PROMUS – an intravascular stent used to treat coronary artery disease – does not infringe any valid claim of U.S. Patent Nos. 7,217,286 ("the '7286 patent"), 7,223,286 ("the '3286 patent"), 7,229,473 ("the '473 patent"), and 7,300,662 ("the '662 patent").[2] Defendant Cordis is the owner of the '7286, '3286 and '473 patents and, along with defendant Wyeth, the co-owner of the '662 patent. Defendants (collectively, "Cordis") have asserted counterclaims alleging that BSC infringes each of the four patents-in-suit. While expert discovery was scheduled to close on August 21, 2009 (*see* D.I. 197),[3] the parties have yet to complete the depositions of all expert witnesses. A hearing on claim construction and summary judgment motions is scheduled for October 30, 2009, with trial scheduled to commence on February 4, 2010.

## III. ARGUMENT

Cordis's motion for partial summary judgment assumes that the Court will agree with Cordis as to the meaning of each disputed claim term in claim 9, an assumption that cannot be justified. As set forth in BSC's Opening *Markman* Brief (D.I. 254) and Responsive *Markman* Brief, substantial intrinsic evidence supports BSC's claim construction positions. In contrast,

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[2] The PROMUS stent is a private label version of the XIENCE V everolimus-eluting coronary stent ("the XIENCE stent"), manufactured by Abbott Laboratories. (D.I. 263 at Ex. 19, BSC-SJA-0716.)

[3] All references to Docket Item numbers are in Civil Action No. 07-333-SLR.

Cordis's proposed constructions frequently depart from the intrinsic evidence and, in some cases, from the claim language itself. In bringing the present motion, Cordis must count on the Court's universal agreement with Cordis on all claim construction issues. If, on the other hand, the Court agrees with BSC as to the meaning of a single disputed claim term in claim 1 or 9, then the PROMUS stent does not infringe.[4]

### A. PROMUS Does Not Possess A Drug "Coating" Under The Proper Construction

Cordis incorrectly asserts that the PROMUS stent has a singular "coating" formed of "an initial primer layer of [PBMA] and a second layer made from a mixture of PVDF-HFP and the drug everolimus." (D.I. 268 at 2.) In actuality, this "coating" represents two distinct layers, one superimposed over the other; only the non-drug-carrying layer can be properly described as a "coating."

The undisputed evidence shows that a drug-free poly (n-butyl methacrylate) ("PBMA") primer coating is first deposited directly onto the bare metal PROMUS stent. (D.I. 263 at BSC-SJA-0717.) Next, a layer of vinylidene fluoride and hexafluoropropylene copolymer ("PVDF-HFP"), co-formulated with the drug everolimus, is applied on top of the PBMA primer coating to form a PVDF-HFP/everolimus mixture. (*Id.*) No topcoat is used. (*Id.*) PBMA and PVDF-HFP, whose structures are set forth below, are chemically distinct:

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[4] Summary judgment is appropriate only if the moving party, "in a properly supported motion, demonstrates that there is 'no genuine issue of material fact,' and that it is entitled to judgment in its favor as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). In determining whether a genuine issue exists for trial, the court must view all inferences drawn from the facts in the light most favorable to the non-moving party, in this case BSC. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986). In order to prevail on an assertion of literal infringement, the patentee must establish that every single limitation of its patent claim is met by the accused product. *See Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998). Where even one limitation in the claims is missing from the accused product or is not met as claimed, there is no literal infringement. *Id.* at 1211.

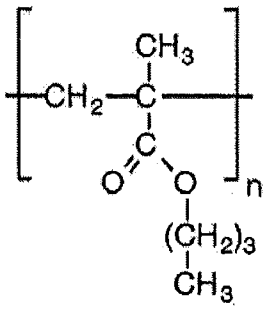
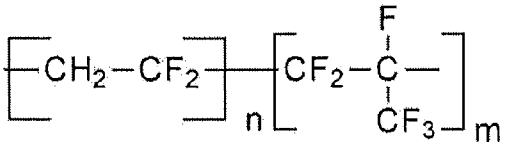
| PBMA | PVDF-HFP |
|---|---|
|  |  |

**Figure 1 – Structure of PBMA and PVDF-HFP**

(*Id.* at BSC-SJA-0718.) For the term "coating" to have any cogent meaning, it must be understood to mean "a distinct covering layer of a particular composition." (*See* D.I. 254 at 24-26.) Otherwise, there would be no plausible distinction between a "coating" of one substance and a "coating" of scores of substances each on top of the other.

**REDACTED**

Thus, when the claims provide examples of "coatings," the "coating" is one layer of a particular composition. (*Id.* at 7:50-53 ("a stent having a coating applied thereto, wherein said coating comprises a biocompatible polymer/drug mixture…"); *see* claim 11 ("wherein the coating comprises a lactone-based polyester").) Similarly, the specification of the '3286 patent refers to a "polymeric coating containing macrocyclic lactone," again suggesting a singular, distinct coating. (*Id.* (BSC-SJA-0021) at Abstract; *see* Declaration of Harold B. Hopfenburg, Ph.D. (submitted herewith) ("Hopfenburg Decl.") Ex. B, ¶¶ 70-74.)

In the case of PROMUS, the PBMA layer covering the stent is not a polymer/drug mixture. It is, moreover, a separate composition than the PVDF-HFP/everolimus mixture superimposed upon it. As a consequence, PROMUS cannot be said to possess the drug "coating" required in claim 9.

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**REDACTED**

**REDACTED**

*See Trilogy Commc'ns, Inc. v. Times Fiber Commc'ns, Inc.*, 109 F.3d 739, 744-45 (Fed. Cir. 1997) (striking the expert reports and affidavits in support of a summary judgment motion that incorporated untimely new opinions); *Astrazeneca AB v. Mut. Pharm. Co.*, 278 F. Supp. 2d 491, 508-10 (E.D. Pa. 2003) (excluding expert declarations submitted with motion for summary judgment because the declarations were actually supplemental expert reports containing new opinions).

### B. The PVDF-HFP Drug Layer Is Not "Applied [To]" The PROMUS Stent Under The Proper Construction

**REDACTED**

(*See, e.g.*, D.I. 254 at 26; D.I. 263, Ex. 2 (BSC-SJA-0036) at 3:46-50 ("The conventional approach as been to incorporate the therapeutic agent into a polymer material which is then coated on the stent. The ideal coating material must be able to adhere strongly to the metal stent…").)

**REDACTED**

**REDACTED**

### C. The Copolymer Used In PROMUS Is Not "Biocompatible" Under The Proper Construction Because The Copolymer Used In PROMUS Elicits Some Negative Reaction

**REDACTED**

The '3286 patent makes perfectly plain that, for a polymer to be "biocompatible" in the context of the patent, the polymer must "***not elicit any negative tissue reaction or promote mural thrombosis formation.***" (D.I. 263, Ex. 2 (BSC-SJA-0037) at 6:34-36 (emphasis added); *see id.* at 3:56-58 ("the coating material should not contribute to *any* adverse response by the body (*i.e.*, should be non-thrombogenic, non-inflammatory, etc.")).) In so defining "biocompatible," Cordis acted as its own lexicographer, expressly narrowing a claim term whose conventional meaning would normally be less restrictive. *See, e.g.*, *Helmsderfer v. Bobrick*

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[5] **REDACTED**

[6] **REDACTED**

*Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008) ("A patentee may act as its own lexicographer and assign to a term a unique definition that is different from its ordinary and customary meaning..."). The PROMUS stent, like any other foreign object inserted into the body, causes some amount of inflammation (although this amount of inflammation was deemed clinically acceptable). (*See* D.I. 263, Ex. 25 at BSC-SJA-0835 (XIENCE stent causes tissue inflammation when implanted in animal coronary arteries.) Accordingly, the PROMUS stent does not meet this limitation of Claim 1.

### D. PROMUS Does Not Possess A "Polymer/Drug Mixture" Under The Proper Construction

Claim 9 of the '3286 patent also requires that the claimed drug coating be a "polymer/drug mixture." Neither the PBMA primer layer nor the PVDF-HFP drug layer on top of it can be said to be a "polymer/drug mixture," however. The actual coating – the PBMA primer – is a homopolymer. It does not contain any drug or drug mixture.

Even if the separate PVDF-HFP drug layer on top of the PBMA layer is considered to be the "coating," it still would not constitute a "***polymer***/drug mixture" because PVDF-HFP is a copolymer, not a "polymer" as defined in the '3286 patent. **REDACTED**

Whether or not this argument has some basis in chemistry, it is clearly contrary to the actual language of the claims in the '3286 patent where "polymer" and "copolymer" are explicitly distinguished. (*See, e.g.*, D.I. 263, Ex. 2

[7] **REDACTED**

at 8:8-15 ("coating comprises ... an acrylate based polymer; acrylate based copolymer"); *id.* at 8:36-39 (same); *id.* at 9:6-7 ("[a] stent according to claim 35 wherein the coating further comprises an acrylate based polymer or copolymer").) For these reasons also, PROMUS cannot be said to possess a "polymer/drug mixture," as required by claim 9 of the '3286 patent.

## IV. CONCLUSION

For the foregoing reasons, BSC respectfully requests that the Court deny Cordis's motion for partial summary judgment of infringement of claim 9 of the '3286 patent.

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**CERTIFICATE OF SERVICE**

I, Andrew A. Lundgren, Esquire, hereby certify that on October 19, 2009, I caused to be electronically filed a copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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